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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,099	09/28/2007	Andrew Pacey	697.031US1	8909

21186 7590 01/25/2010

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EXAMINER	
KETTER, JAMES S	

ART UNIT	PAPER NUMBER
1636	

NOTIFICATION DATE	DELIVERY MODE
01/25/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

uspto@slwip.com
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Office Action Summary	Application No.	Applicant(s)	
	10/594,099	PACEY, ANDREW	
	Examiner	Art Unit	
	James S. Ketter	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 October 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *2 and 12-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 September 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/25/06;9/28/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicant's election without traverse of Group I, claims 1 and 3-11, in the reply filed on 29 October 2009 is acknowledged.

Claims 2 and 12-19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 29 October 2009.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 3-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Wolff et al. (A, newly cited).

Claim 1 is drawn to a method for introducing nucleic acid into cells of a region of the human or animal body, which method comprises substantially occluding an efferent vessel from said body region and introducing said nucleic into that body region under pressure via said efferent vessel. Claim 3 specifies within claim 1 that said region of the body is an organ of the body. Claim 4 specifies within claim 3 that the organ is selected from the list comprising kidney, heart, spleen, pancreas, lung, adrenal glands, stomach, prostate gland and ovary. Claim 5 specifies within claim 4 that the organ is the liver. Claim 6 specifies within claim 1 that the nucleic acid is introduced at a pressure of, or the pressure development means are adapted to

generate a pressure of, 10-80 mmHg. Claim 7 specifies within claim 1 that the nucleic acid is in the form of a plasmid. Claim 8 specifies within claim 1 that occlusion is achieved by or the occluding means comprises one or more balloons. Claim 9 specifies within claim 1 that the nucleic acid is introduced into said region of the body in less than 60 seconds. Claim 10 specifies within claim 1 that the liquid formulation comprising said nucleic acid has a total volume of 50-1300 ml. Claim 11 specifies within claim 10 that the liquid formulation comprising said nucleic acid has a total volume of 75-350 ml.

Wolff et al. teaches, e.g., at the second full paragraph at column 2, "In a preferred embodiment, a process is described for delivering a polynucleotide into an extravascular parenchymal cell of a mammal, comprising selecting a polynucleotide to be delivered, inserting the polynucleotide into a mammalian vessel, such as a blood vessel and increasing the permeability of the vessel such that the polynucleotide is delivered to the parenchymal cell thereby altering endogenous properties of the cell. Increasing the permeability of the vessel comprises increasing pressure against vessel walls. Increasing the pressure consists of injecting an appropriate volume of fluid into the vessel at an appropriate rate. The volume of fluid comprises the polynucleotide in a pharmaceutically acceptable solution into the vessel. The fluid may further comprise a compound which complexes with the polynucleotide. The fluid may further comprise a compound known to cause vessel dilation. The increased pressure is controlled by altering the specific volume of the solution in relation to the specific time period of insertion. Increasing the permeability of a vessel may further comprise inhibiting the flow of fluid through one or more vessels. Increasing the permeability of a vessel may further comprise inhibiting fluid flow or into or out of an organ or limb." Various organs, including liver, as the

target is taught, e.g., at column 3, fourth full paragraph. The paragraph bridging columns 18 and 19 teaches that the nucleic acid may be plasmid. Use of a balloon to occlude the vessel is taught at column 3, first full paragraph. At column 22, second full paragraph, it is taught to inject the nucleic acid in 7 seconds. Also, a formula is disclosed to determine the volume of reagent injected based on patient mass and injection time, which for the normal range of humans would anticipate the volumes of claims 10 and 11. With respect to claim 6, injection using the formula at column 22 would inherently produce a pressure within the range of 10 - 80 mm Hg. Alternatively, an injection would be repeatedly subjected to a pressure equal to the difference between the systolic and diastolic pressures upon injection which would fall within the 10 – 80 mm Hg range for most normal humans.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James S. Ketter whose telephone number is 571-272-0770. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JSK
22 January 2010

/James S. Ketter/
Primary Examiner, Art Unit 1636